

CLAIMS

What is claimed is:

1. A method of treating a disease or condition which is responsive to testosterone therapy comprising the step of:

5 administering a topical testosterone formulation to the skin of a subject, wherein the formulation comprises a modified poloxamer lecithin organogel carrier having admixed therein, an arginine ingredient in an amount of from about 0.1 to about 20% w/w, and a tocopherol ingredient in an amount of from about 0.1 to about 20% w/w; and

10 a therapeutically effective amount of micronized testosterone.

2. The method of claim 1, wherein said disease or condition is AIDS Wasting Syndrome.

15 3. The method of claim 1, wherein said disease or condition is micropenis.

4. The method of claim 1, wherein said disease or condition is a member selected from the group consisting of: somatopause, andropause, viropause, or androgen deficiency in adult males (ADAM).

20 5. The method of claim 1, wherein said disease or condition is a member selected from the group consisting of: anemia from renal dialysis or chronic kidney disease.

25 6. The method of claim 1, wherein said disease or condition is benign prostatic hyperplasia.

7. The method of claim 1, wherein said disease or condition is a member selected from the group consisting of: acne, diabetes, infertility, periodontal disease, post anabolic steroid abuse, dry eyes, diabetic retinopathy, retinopathy, and lupus erythematosus.

30 8. The method of claim 1, wherein said disease or condition is decreased bone density.

9. The method of claim 1, wherein said disease or condition is hyperlipemia.

10. The method of claim 1, wherein the disease or condition is a
5 predisposition toward prostate cancer.

11. The method of claim 1, wherein said disease or condition is a member
selected from the group consisting of: heart disease, angina, and hypertension.

12. The method of claim 1, wherein the disease or condition results in
10 infrequent early morning erections.

13. The method of claim 1, wherein the disease or condition results in small
penis size in prepubertal boys.

14. The method of claim 1, wherein the disease or condition results in
15 subphysiologic levels of insulin-like growth factor (IGF-1).

15. The method of claim 1, wherein the disease or condition results in poor
20 muscle strength, cognitive function, mood, and energy, in the subject.

16. The method of claim 1 wherein the disease or condition is the result of
anabolic steroid abuse.

17. The method of claim 1, wherein the formulation has a testosterone content
25 of about 10% w/w, and administration is a routine of administering from about
0.5g to about 2g of the formulation once a day on a daily basis for at least about
30 days.

18. The method of claim 17, wherein the administration achieves a serum
30 testosterone level of from about 600 ng/dl to about 1200 ng/dl.

19. The method of claim 1, wherein the administration comprises applying
the formulation to hairless skin along the rib area below the armpit and the

underarm and/or to the scrotal skin.

5 20. The method of claim 1, wherein the administration results in peak levels of serum or salivary testosterone within about 24 to about 36 hours after application.

10 21. The method of claim 1, wherein the administration results in sufficiently high salivary levels of free testosterone and dihydrotestosterone to prevent the conversion of excess testosterone to estradiol.

22. A method of temporarily and reversibly decreasing sperm count comprising the step of:

15 administering a topical testosterone formulation to the skin of a male, wherein the formulation comprises a modified poloxamer lecithin organogel carrier having admixed therein, an arginine ingredient in an amount of from about 0.1 to about 20% w/w, and a tocopherol ingredient in an amount of from about 0.1 to about 20% w/w, and a therapeutically effective amount of micronized testosterone.

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